

Application No. 09/689,139
VAS Ref. S63.2-9178

Amendment and Response
Page 3

Rejections

35 U.S.C. §112

Claim 15 has been rejected under 35 U.S.C. §112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Office Action asserts that there is insufficient antecedent basis in claim 13 for the limitation "catheter balloon of claim 13" in line 1 of claim 15.

Claim 15 has been amended so that the antecedent basis is correct. Applicants respectfully request that the rejection of claim 15 under 35 U.S.C. §112 be withdrawn.

35 U.S.C. §103(a)

Claims 1-4, 8-13, 15-17 and 19 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Wang et al. (US 5,348,538) in view of Fritz et al. (US 5,735,830).

Applicants traverse the rejection.

The present invention relates to a medical device including a dilatation balloon. The dilatation balloon is formed from a crosslinked polymeric material which is the reaction product of at least one polymer and at least one hydrolysable silane.

The Office Action asserts that Wang teaches the production of balloon catheters from polyethylenes, and that Fritz teaches the production of medical instruments such as catheters, from compositions containing polyethylene that is grafted with silane and then crosslinked with water to produce Si-O-Si-O links in the final products.

The Office Action further asserts that the patents are analogous because both deal with the production of catheters from polyethylene-based formulations and that it would have been obvious to employ the compositions of Fritz to make the balloon catheters of Wang in order to make them transparent and steam sterilizable.

Application No. 09/689,139
VAS Ref. S63.2-9178

Amendment and Response
Page 4

Wang et al., US 5,348,538

Wang et al. teaches a new and unique single layer balloon catheter which has a hybrid compliance curve that includes both compliant and non compliant portions and a method of making the same. A benefit of the hybrid compliant balloon is that advantages of both the compliant and the non-compliant balloons can be obtained in a single catheter that can be sized to the artery by varying the inflation pressure. See col. 4, lines 18-33.

Fritz et al., US 5,735,830

Fritz teaches a polymer material formed from a first polyethylene component having low density and/or a second polyethylene component having extreme low density, whereby an organic silane is grafted to the polymer material with the addition of an organic peroxide and the grafted polymer is cross-linked through storage in a humid environment and/or water (col. 1, lines 63-66 and col. 2, lines 1-4).

Fritz suggests catheters, tubes, tracheal tubes, and the like (col. 1, lines 14-16). Fritz makes no suggestion that the compositions described therein could be employed in the formation of *dilatation balloons*. Formation of dilatation balloons requires further processing than extruding catheters and tubes.

The present invention is directed to a composition and method for forming *dilatation balloons* employing a crosslinked composition. As noted above, formation of balloons requires additional processing steps than extruding catheters and tubes. Furthermore, balloons have certain physical characteristic requirements which are different from those of catheter tubing.

The Office Action states on page 5, 3rd paragraph that the motivation to employ the compositions of Wang is found at col. 2, lines 29-31 of Fritz, where the transparency and steam sterilizability of the Fritz products are disclosed. In the Office Action it is stated that it is desirable to make balloon catheters that are transparent and steam sterilizable so that the catheters do not obscure other objects in x-rays after they are inserted in to the body and so that they may be sterilizable using conventional steam sterilizing devices.

Application No. 09/689,139
VAS Ref. S63.2-9178

Amendment and Response
Page 5

Applicants disagree. Applicants submit that neither transparency nor steam sterilizability are properties which are discussed in Wang et al. or in the present specification. Applicants submit that transparency and steam sterilizability are not motivating factors in the development of dilatation balloons as described in the present invention.

Applicants submit that in contrast to that proposed in the Official Action, the transparency or opacity of a material as discussed in Fritz et al. is irrelevant to x-rays, and that transparency as described in Fritz et al. relates to the visible range, not to the x-ray range. Fritz et al. in fact do not even mention x-rays. X-rays penetrate *visibly opaque* materials as well as *visibly transparent* materials, and are in fact able to penetrate through the body. Thus, there is no advantage in selecting a visibly transparent polymer over a visibly opaque polymer when using such polymers in the presence of x-rays. Consequently, Applicants do not see transparency as a motivating factor, and it is in fact unclear as to why the transparency of a material in relation to x-rays is being suggested by the Official Action as a motivating factor.

Wang et al. discusses the desirability of having balloons with hybrid compliance. See cols. 1-5. The present invention discusses the desirability of having toughness, abrasion resistance, durability, dimensional stability, and resistance to pinholes and ruptures. See the Field of the Invention, page 2, lines 15-17, page 3, lines 25-29). Steam sterilizability nor transparency are discussed.

Therefore, the properties of transparency and steam sterilizability of the compositions as discussed in Fritz et al., provide no motivation to combine Wang et al. with Fritz et al. The problems to be solved in each are different from each other, and different from those as discussed in the present invention.

Case law suggests that there in order to sustain a holding obviousness, one must first show that there is some suggestion, teaching or motivation to combine the prior art references, and that also there be a reasonable likelihood of success. *Brown & Williamson Tobacco Corp. v. Philip Morris Inc.*, 56 USPQ2d 1456, 1459 (CA FC 2000) (quoting *C.R. Bard, Inc. v. M3 Sys. Inc.*, 157 F.3d 1340, 1352, 48 USPQ2d 1225, 1232 (Fed. Cir. 1998)).

This evidence may flow from the prior art references themselves, the knowledge

Application No. 09/689,139
VAS Ref. S63.2-9178

Amendment and Response
Page 6

of one of ordinary skill in the art, or, in some cases, from the nature of the problem to be solved. *Brown & Williamson Tobacco Corp. v. Philip Morris Inc.* at 1459 (referring to *Pro-Mold & Tool Co. v. Great Lakes Plastics, Inc.*, 75 F.3d 1568, 1573, 37 USPQ2d 1626, 1630 (Fed. Cir. 1996)).

Applicants submit that the references, when viewed as a whole, provide no motivation to combine the references in this instance, and thus to employ the compositions of Fritz et al. in the balloon catheters of Wang et al. Applicants respectfully request withdrawal of the 35 U.S.C. §103(a) rejection of claims 1-4, 8-13, 15-17 and 19 as being unpatentable over Wang et al. (US 5,348,538) in view of Fritz et al. (US 5,735,830).

Claims 5-7, 14 and 18 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Wang et al. in view of Schmid (US 5,055,249).

Applicants traverse the rejection.

The Office Action submits that Wang et al. teach the use of polyamides (col. 2, lines 32, 40 and 46) to make balloon catheters (title), but that Wang fails to teach the amino functional polymer/silane combinations recited in these claims.

The Office Action submits that Schmid teaches that glycidylxypropyltrimethoxysilane (col. 6, line 60) is among the silanes that react with the amino groups (col. 1, lines 53-55) in formulations containing polyamides (col. 1, line 42), to yield crosslinked polyamide articles (title) which have improved mechanical and fire resistance properties (abstract).

Schmid, US 5,055,249

Schmid describes a process for the preparation of crosslinked shapes from a polymer which consists of reacting a starting polyamide with a particular silane. The polyamide should have at least 30% by weight of branched polymer chains, but these may be furnished by adding branching agents to the monomers before or during polymerization. After the reaction with silane has taken place, the polymer is molded or otherwise formed into desired shapes and brought into contact with water. This causes three dimensional crosslinking of the polymer and provides improved mechanical and fire resistant properties to the finished product (Abstract).

Application No. 09/689,139
VAS Ref. S63.2-9178

Amendment and Response
Page 7

Schmid makes no comment as to the type of articles which may be formed, or to the mechanical properties which have been improved. Thus, there is no reference whatsoever to balloon catheters. Fire resistance has no relevance to medical devices for noninvasive surgical procedures, including balloon catheters, as described in the present invention.

The only indication that Schmid makes as to what types of shaped articles may be formed is at col. 1, lines 34-40 where Schmid states that the new types of polyamides do not satisfy all the requirements, especially for construction elements, tools, wear-resistant shaped articles such as cable sheaths, or materials with very high creep resistance and toughness, but that it is an object of the invention to provide polyamide shaped articles with more highly improved mechanical properties. It can only be surmised as to what these mechanical properties may be.

Wang et al. has been discussed above.

The Office Action asserts that it would have been obvious to one having ordinary skill in the art at the time that the invention was made to employ the polyamide- and silane-containing formulations of Schmid in the production of the balloon catheters of Wang et al. in order to give them improved mechanical and fire resistance properties.

Applicants disagree. Schmid gives no direction at all as to what these improved mechanical properties are, and makes no reference whatsoever that the compositions as disclosed therein, would be useful for any type of medical device, much less a balloon catheter. The only reference Schmid makes to any specific articles, is included with a statement that the new polyamides do not meet the requirements for such articles (col. 1, lines 34-41). There is thus no suggestion whatsoever that the compositions may be employed in dilatation balloons.

Applicants submit that dilatation balloons require very specific properties not required by extruded tubing such as catheter tubing. For example, because they are inflated under pressure, and can only be inflated to a specific size, not larger than a patient's vasculature into which it is being inserted, they must have very specific expansion characteristics and burst strengths. Furthermore, it is important that no holes or ruptures form in such balloons. They must have abrasion resistance and puncture resistance, resistance to pinhole formation, durability, and so forth.

Application No. 09/689,139
VAS Ref. S63.2-9178

Amendment and Response
Page 8

Applicants submit that neither Wang et al., nor the specification of the above-referenced patent application, make reference to the property of fire resistance, and that it is not a property which one typically strives to impart to a dilatation balloon.

Because Schmid gives no guidance as to what mechanical properties are achieved, nor as to what "shaped articles" may be formed from the compositions, other than to indicate what articles the compositions *may not* be useful for (col. 1, lines 34-41), and because dilatation balloons require that certain properties be met, Applicants submit that there would be no motivation to employ the compositions of Schmid in the balloon catheters of Wang et al.

The Office Action argues that "[t]he motivation to employ the polyamide- and silane-containing formulations of Schmid in the production of the balloon catheters of Wang et al. is found in the abstract of Schmid, where the improved mechanical and fire resistance properties of Schmid's articles are discussed. It is deemed desirable to make balloon catheters that are mechanically strong and fire retardant in order to improve the useful life of the balloon catheters (because of their improved mechanical strength) and to facilitate their storage (because of their fire resistance)."

However, as discussed above, there must be some suggestion, teaching, or motivation to combine the references, as well as a reasonable likelihood of success. As there is no guidance in Schmid as to what mechanical properties have been improved, nor is there any direction as to what shaped articles the compositions find utility in, there would be no motivation to employ the compositions in the dilatation balloon, nor could there be any reasonable expectation that the compositions may successfully be used to make dilatation balloons. Improved mechanical properties could refer to a variety of properties that may have no relevance to a dilatation member. Fire resistance, the one property mentioned, is of little importance in the manufacture of these balloons.

Based on the foregoing amendments and arguments, Applicants respectfully request withdrawal of the rejection of claims 5-7, 14 and 18 have been under 35 U.S.C. §103(a) as being unpatentable over Wang et al. in view of Schmid (US 5055249).

Application No. 09/689,139
VAS Ref. S63.2-9178

Amendment and Response
Page 9

CONCLUSION

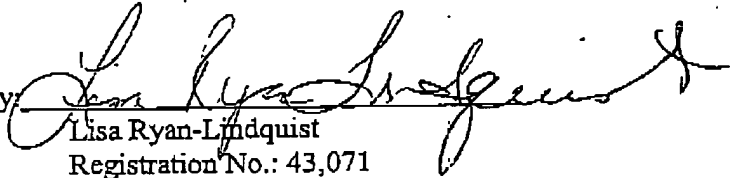
Applicants have addressed each of the issues presented by the Office Action. Claims 1-19 and 31 are pending in the application. Based on the foregoing arguments and amendments, Applicants respectfully request reconsideration and an early allowance of the claims as presented.

Respectfully submitted,

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Application No. 09/689,139
VAS Ref. S63.2-9178

Amendment and Response
Page 10

MARKED UP VERSION TO SHOW CHANGES MADE

15. (Amended) The [catheter] balloon catheter of Claim 13 wherein Y is an alkoxy of C₁ to C₄.